CHAPTER 13
STANDARDS OF PRACTICE AND PRINCIPLES OF MEDICAL ETHICS

[Prior to 5/4/88, see 470—135.251 to 470—135.402]

653—13.1(148,272C) Standards of practice—packaging, labeling and records of prescription drugs dispensed by a physician.

13.1(1) A physician shall dispense a prescription drug only in a container which meets the requirements of the Poison Prevention Packaging Act of 1970, 15 U.S.C. ss. 1471-1476 (2001), unless otherwise requested by the patient, and of Section 502G of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. ss. 301 et seq. (2001).

13.1(2) A label shall be affixed to a container in which a prescription drug is dispensed by a physician which shall include:

1. The name and address of the physician.
2. The name of the patient.
3. The date dispensed.
4. The directions for administering the prescription drug and any cautionary statement deemed appropriate by the physician.
5. The name and strength of the prescription drug in the container.

13.1(3) The provisions of subrules 13.1(1) and 13.1(2) shall not apply to packaged drug samples.

13.1(4) A physician shall keep a record of all prescription drugs dispensed by the physician to a patient which shall contain the information required by subrule 13.1(2) to be included on the label. Noting such information on the patient's chart or record maintained by the physician is sufficient.

This rule is intended to implement Iowa Code sections 147.55, 148.6, 272C.3 and 272C.4.

653—13.2(148,150,150A,272C) Standards of practice—prescribing or administering controlled substances for the treatment of patients with chronic, nonmalignant pain. This rule establishes standards of practice for the management of chronic, nonmalignant pain. The purpose of the rule is to assist physicians who prescribe and administer drugs to provide relief and eliminate suffering in patients with chronic, nonmalignant pain as defined in this rule.

13.2(1) *Definitions.* As used in this rule:

"Agency for Healthcare Research and Quality" or *"AHRQ"* means the agency within the U.S. Department of Health and Human Services which is responsible for establishing Clinical Practice Guidelines on various aspects of medical practice.

"American Academy of Pain Medicine" or *"AAPM"* means the American Medical Associationrecognized specialty society of physicians who practice pain medicine in the United States. The mission of the AAPM is to enhance pain medicine practice by promoting a climate conducive to the effective and efficient practice of pain medicine.

"American Pain Society" or *"APS"* means the national chapter of the International Association for the Study of Pain, an organization composed of physicians, nurses, psychologists, scientists and other professionals who have an interest in the study and treatment of pain. The mission of the APS is to serve people in pain by advancing research, education, treatment and professional practice.

"Chronic, nonmalignant pain (i.e., not caused by cancer)" means persistent or episodic pain of a duration or intensity that adversely affects the functioning or well-being of a patient when (1) no relief or cure for the cause of pain is possible; (2) no relief or cure for the cause of pain has been found; or (3) relief or cure for the cause of pain through other medical procedures would adversely affect the wellbeing of the patient.

13.2(2) *General provisions.* Various controlled drugs, particularly opioid analgesics, can be safely and effectively utilized to control pain in certain patients. However, inappropriate prescribing of controlled substances can lead to, or accelerate, drug abuse and diversion. Therefore, the medical management of pain shall be based on a thorough knowledge of pain assessment, pain treatment, and concern for the patient.

a. Treatment of acute pain and cancer pain. Physicians may refer to the Clinical Practice Guidelines published by the AHRQ for counsel on the proper treatment of acute pain and chronic pain associated with cancer. The AHRQ Clinical Practice Guidelines provide a sound, compassionate, and flexible approach to the management of pain in these patients.

b. Treatment of chronic, nonmalignant pain. The basic premise underlying this rule is that various drugs, particularly opioid analgesics, may be useful for treating patients with chronic, nonmalignant pain in a safe, effective, and efficient manner when other efforts, including those by other practitioners or the patient, have failed to remove or effectively treat the pain. The board strongly recommends that physicians who have reservations about the use of drugs in the treatment of chronic, nonmalignant pain consult: Definitions Related to the Use of Opioids for the Treatment of Pain, a consensus

document from the American Academy of Pain Medicine (AAPM), the American Pain Society (APS), and the American Society of Addiction Medicine (ASAM) (2001). Copies of the document are available from the AAPM (http://www.painmed.org), the APS (http://www.ampainsoc.org), the ASAM (http://www.asam.org), and the office of the board at 400 S.W. 8th Street, Suite C, Des Moines, Iowa 50309-4686.

13.2(3) *Effective chronic, nonmalignant pain management.* To ensure that pain is properly and promptly assessed and treated, a physician who prescribes or administers controlled substances to a patient for the treatment of chronic, nonmalignant pain shall exercise sound clinical judgment by establishing an effective pain management plan in accordance with the following:

a. Patient evaluation. A patient evaluation that includes a physical examination and a comprehensive medical history shall be conducted prior to the initiation of treatment. The evaluation shall also include an assessment of the pain, physical and psychological function, diagnostic studies, previous interventions, including medication history, substance abuse history and any underlying or coexisting conditions. Consultation/referral to a physician with expertise in pain medicine, addiction medicine or substance abuse counseling or a physician who specializes in the treatment of the area, system, or organ perceived to be the source of the pain may be warranted depending upon the expertise of the physician and the complexity of the presenting patient. Interdisciplinary evaluation is strongly encouraged.

b. Treatment plan. The physician shall establish a comprehensive treatment plan that tailors drug therapy to the individual needs of the patient. To ensure proper evaluation of the success of the treatment, the plan shall clearly state the objectives of the treatment, for example, pain relief, or improved physical or psychosocial functioning. The treatment plan shall also indicate if any further diagnostic evaluations or treatments are planned and their purposes. The treatment plan shall also identify any other treatment modalities and rehabilitation programs utilized.

c. Informed consent. The physician shall document discussion of the risks and benefits of controlled substances with the patient or person representing the patient.

d. Periodic review. The physician shall periodically review the course of drug treatment of the patient and the etiology of the pain. Modification or continuation of drug therapy by the physician shall be dependent upon evaluation of the patient's progress toward the objectives established in the treatment plan. The physician shall consider the appropriateness of continuing drug therapy and the use of other treatment modalities if periodic reviews indicate the objectives of the treatment plan are not being met or there is evidence of diversion or a pattern of substance abuse.

e. Consultation/referral. The physician shall consider consultation with, or referral to, a physician with expertise in pain medicine, addiction medicine or substance abuse counseling, if the objectives of the treatment plan are not being met or there is evidence of diversion or a pattern of substance abuse.

f. Documentation. The physician shall keep accurate, timely, and complete records that detail compliance with this subrule, including patient evaluation, diagnostic studies, treatment modalities, treatment plan, informed consent, periodic review, consultation, and any other relevant information about the patient's condition and treatment.

g. Physician-patient agreements. Physicians treating patients at risk for substance abuse shall consider establishing physician-patient agreements that specify the rules for medication use and the consequences for misuse. In preparing agreements, a physician shall evaluate the case of each patient on its own merits, taking into account the nature of the risks to the patient and the potential benefits of treatment.

h. Termination of care. The physician shall consider termination of patient care if there is evidence of diversion or a repeated pattern of substance abuse.